STS/ACC TVT Registry™

An initiative of the STS National Database and the ACC's NCDR

Participant Companion Guide for Public Reporting

The mission of the TVT Registry™ is to track patient safety and real-world outcomes related to transcatheter valve replacement or repair procedures. The registry is an initiative of the Society of Thoracic Surgeons (STS) and the American College of Cardiology Foundation (ACCF).

Table of Contents

IMPORTANT Notes:

A. ***A four-part guide to assist in the understanding of risk models in the hospital's outcome reports is located on participant login section of the TVT Registry. Go to Resources – Documents to review these guides.***

B. ***If a facility has no data in the risk standardized outcome metrics, inclusion criteria has not been met (see inclusion specifications).***

Last update: 11/8/2021

TAVR Volume Metric

Report example:

The Society of Thoracic Surgeons

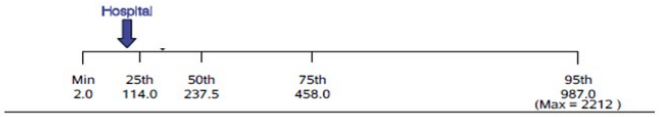
STS/ACC TVT Registry

Public Reporting Metrics

Patients with TAVR as of 2019 q4

Hospital ABC (123456)

AMERICAN COLLEGE of CARDIOLOGY

Timeframe First TAVR Procedure Performed	My Hospital TAVR Volume[1] (commercial procedures only)		Distribution of Annual Hospital TAVR Volumes (Across all TVT Registry Hospitals)
	Cumulative	Annual volume (Jan 1 to Dec 31, 2019)	
Dec, 2011	750	60	

1. Month and year the first procedure was submitted to Registry
2. Cumulative volume since enrollment
3. Annual volume (most recent last four quarters)
4. Site volume as compared to volume across all registry hospitals (distribution diagram)

TAVR 30-Day Morbidity/Mortality Composite:

The TAVR 30-day morbidity/mortality composite was developed by a TVT Registry Workgroup (physician leaders of the registry and statisticians at Duke Clinical Research Institute) for the purpose of providing feedback in the institutional outcome reports. The model is a hierarchical, multi-category risk model that estimates risk standardized results (reported as a "site difference" and including the calculation of 1-3 stars for public reporting) for 5 endpoints (outcomes) at 30 days (mortality, stroke, major or life-threatening bleeding, acute kidney injury, or moderate-severe paravalvular aortic regurgitation). If a patient experiences multiple outcomes, the outcome with the highest rank is assigned. The model includes 46 variables including KCCQ and gait speed (5-meter walk) and is reported on **rolling 3 years** of data (not R4Q).

Report example:

The Society of Thoracic Surgeons

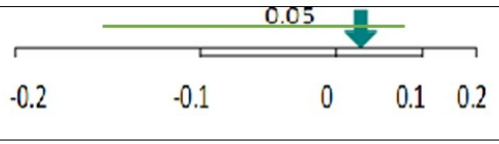
STS/ACC TVT Registry

Public Reporting Metrics

Patients with TAVR as of 2019 q4

Hospital ABC (123456)

AMERICAN COLLEGE of CARDIOLOGY

My Hospital TAVR 30 Day Composite Site Difference [1,2,3] (95% Confidence Intervals)	**Eligible Patients** (Jan 1, 2017 –Dec 31, 2019)	**Participant Rating**	**Distribution of Participant Estimates**
0.05 (-0.15 to 0.12)	160	★★	

[1] Missing value (--) indicates that hospital does not meet eligibility criteria for reporting.

[2] 30 Day Composite consists of six ordered categories based on the worst possible outcome (30-day death) to the best possible outcome (e.g. alive and free of major complications) during hospitalization and the 30-day follow-up period as defined below:

1. 30-day death
2. 30-day stroke
3. 30-day life-threatening/major bleed
4. Acute kidney injury (stage III)
5. 30-day >=2+ (mod-sev) paravalvular leak
6. None of the above

[3] The TAVR 30-day Mortality/morbidity composite is reported as a "win difference"

>0 implies "My Hospital" has better than expected performance

<0 implies "My Hospital" has worse than expected performance

Model Specifications

A. **Model Outcomes* ****

1. Mortality (in-hospital or 30 day)
2. Stroke (in-hospital or 30-day ischemic, hemorrhagic, or undetermined stroke)
3. Bleed (in-hospital or 30-day VARC major/life threatening bleed)
4. Acute Kidney Injury (in-hospital AKI stage III, or in-hospital/30-day new dialysis)
5. Paravalvular Aortic Regurgitation (in-hospital or 30-day moderate to severe paravalvular regurgitation)

*If one patient experiences multiple outcomes, the outcome with the highest rank is assigned.
**Table 1 defines model outcome definitions

B. **Timeframe:** Rolling 3-years with a lag of the published reporting timeframe by one quarter (to assure data completeness in the 30-day endpoints). For example, 2020q4 report includes patients discharged from 2017q4 to 2020q3.

C. **Model Eligibility and Population Definition**

a. Model eligibility at the *facility* level:
   i. "Green" or "Yellow" "Data Quality Report" data submissions (base and follow-up).
   ii. Site must have >=90% completeness of the following items across the rolling 3-year reporting period:
      1. Computed baseline Kansas City Cardiomyopathy Questionnaire (KCCQ – 13846-13867) with at least one value for questions 1a-8c)*; **AND**
      2. Baseline 5-meter walk test performed (at least one walk test time 13199-13201 or patient is unable to walk (13191)*, **AND**
      3. Event Status/30-Day Follow-up (patient meets criteria for any endpoint or some follow-up assessment (11000) at least 23 days after procedure start date.

      Note: The >=90% completeness for baseline 5-meter walk and baseline KCCQ was removed for patients discharged from March to December 2020 (the COVID time-period).

   iii. At least 60 TAVR procedures.
   iv. Enrolled and submitted data prior to the rolling 3-year timeframe.

b. Model eligibility at the *patient* level:
    1. Includes index (first) TAVR procedure performed during admission in the rolling year timeframe (excludes subsequent TAVR procedures or episodes in the R3Y timeframe).
    2. Excludes
        a. Patients with lab visit that is NOT a TAVR.
        b. TAVR procedures that are not the first lab visit in the episode of care.
        c. TAVR episodes that are not the first episode in the R3Y timeframe.
        d. Patient record incomplete in event status/30-day follow-up assessment (to capture endpoints of mortality, stroke, AKI and bleeding at 30 days).)
        e. Patients in TVT Registry sponsored research studies (identified with research study=yes and research study device used during procedure).

D. **Variables *(see table 2)***

E. **Report details**

a. **What is a site difference?**

A site difference (also called a "win-difference") is a new method to report risk standardized composite outcomes (fatal and non-fatal). The model provides different weights for each event, based on the clinical importance and timing of the outcomes. It is used in clinical trials that have a composite of primary endpoints and is a newer method that creates the foundation of site rankings.

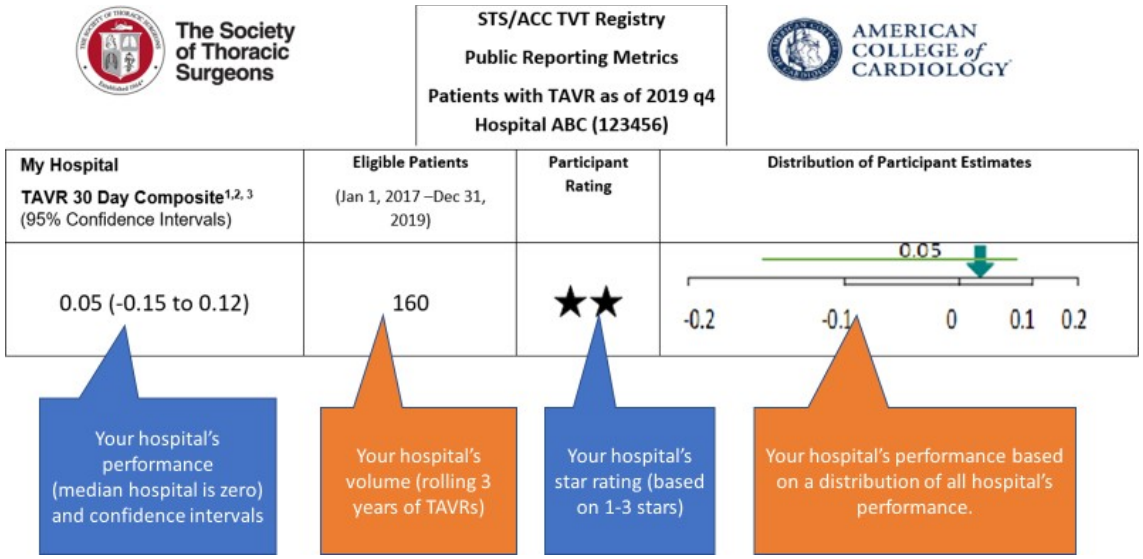
In statistics, a site difference is defined as: The probability that a random patient at your hospital would have a **worse outcome** at an average hospital (vs your hospital) MINUS the probability that a random patient at your hospital would have a **better outcome** at an average hospital (vs your hospital).

A simpler definition is: The probability an average patient is better off going to YOUR hospital (vs an average hospital) MINUS the probability an average patient is better off going to an AVERAGE hospital (vs your hospital)

F. **Site Difference interpretation:**
a. Site Difference >0 (positive number) implies that a random patient is better off at your hospital (vs an average hospital). Your hospital has better than expected performance.

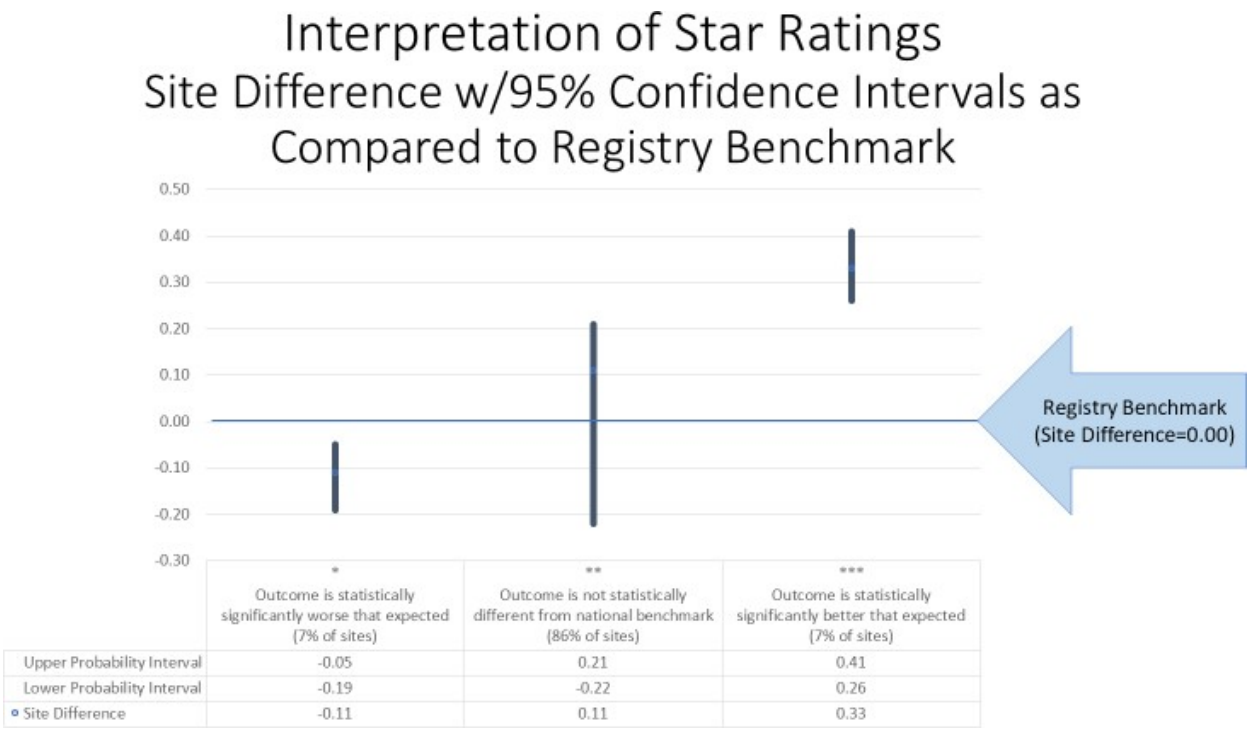
b. Site Difference <0 (negative number) implies that a random patient is better off at an average hospital (not your hospital). Your hospital has worse than expected performance.

Site Difference Equation	Site A (better than average)	Site B (worse than average)
An average patient is better off going to YOUR hospital (vs an average hospital)	0.2	0.1
Subtracted by	minus	minus
An average patient is better off going to an AVERAGE hospital (vs your hospital)	0.1	0.2
equals	=	=
Site Difference	0.1	-0.1
	Positive site difference implies better than average performance	**Negative site difference implies worse than average performance**



Last update: 11/8/2021

G. **Interpretation of Star Ratings**



	* Outcome is statistically significantly worse that expected (7% of sites)	** Outcome is not statistically different from national benchmark (86% of sites)	*** Outcome is statistically significantly better that expected (7% of sites)
Upper Probability Interval	-0.05	0.21	0.41
Lower Probability Interval	-0.19	-0.22	0.26
Site Difference	-0.11	0.11	0.33

Star ratings:

1. * Your site difference and confidence intervals (CI) are all <0 (negative numbers). This implies your hospital has worse than expected performance.
2. ** Your hospitals CI cross zero. This implies your hospital's performance is not different from the registry benchmark (this includes about 86-87% of all hospitals).
3. *** Your site difference and CI are all >0 (positive numbers). This implies your hospital has better than expected performance.

Last update: 11/8/2021

H. Additional Report Details (page 2 of pdf)

a. TAVR 30-Day Composite Details: This provides the count of patients at your hospital in each composite outcome category. Note that if a patient has more than one outcome, they are categorized in the worst outcome category.

TAVR 30-Day Composite Details

Number of patients with "worst" observed outcome in each composite outcome category at your hospital

Composite Outcome Category	My Hospital		Registry	
	Number	Percent	Number	Percent
Death (30 day)	4	2.5%	1671	3.2%
Stroke (30 day)	1	0.6%	1077	2.0%
Life threatening/major bleeding (30 day)	8	5.0%	3024	5.8%
Acute kidney injury (in-hospital AKI stage III or 30-day new dialysis)	2	1.3%	336	0.6%
>=2+ (mod-sev) paravalvular leak (30 days)	4	2.5%	1304	2.5%
None of the above	141	100.0%	45149	85.9%

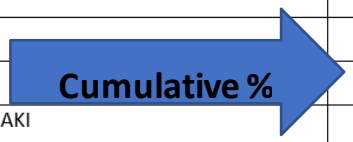
b. Comparison of observed and expected outcomes for cumulative outcome categories at your hospital: This table provides the observed, expected and O/E ratio for all model outcomes for your hospital. This will help you determine which outcome category you may need to improve your Hospital's performance in (any O/E ratio and/or CI range >1.0).

Number of patients with "worst" observed outcome in each composite outcome category at your hospital

Composite Outcome Category	My Hospital		Registry	
	Number	Percent	Number	Percent
Death (30 day)	4	2.5%	1671	3.2%
Stroke (30 day)	1	0.6%	1077	2.0%
Life threatening/major bleeding (30 day)	8	5.0%	3024	5.8%
Acute kidney injury (in-hospital AKI stage III or 30-day new dialysis)	2	1.3%	336	0.6%
>=2+ (mod-sev) paravalvular leak (30 days)	4	2.5%	1304	2.5%
None of the above	141	100.0%	45149	85.9%

Comparison of observed and expected outcome for cumulative outcome categories at your hospital

Composite Cumulative Outcomes	Observed (%)	Expected (%)	O / E Ratio
Death	2.5%	2.4%	1.0 (0.3-1.2)
Death or Stroke	3.1%	3.1%	1.0 (0.6-1.3)
Death or Stroke or Bleeding	8.1%	8.8%	0.9 (0.5-1.1)
Death or Stroke or Bleeding or AKI	9.4%	9.6%	1.0 (0.4-1.5)
Death or Stroke or Bleeding or AKI or PVL	11.9%	12.2%	0.9 (0.7-1.4)



Last update: 11/8/2021

TABLE 1: Composite Model Endpoint Definitions:

A. **30 Day Death -** If and only if any of the below criteria are met:

1. Patient died in-hospital (#10105 = Deceased) with Discharge Date (#10100) within 0-30 days of Procedure Start Date (#7000).
2. Patient died in-follow-up (#10004 = Deceased) with Date of Death (#11006) within 0-30 days of Procedure Start Date (#7000).
3. Patient died in-follow-up (#10004 = Deceased) with Date of Death (#11006) missing and Date of Assessment (#11000) within 0-75 days of Procedure Start Date (#7000).

B. **30 Day Stroke**

Using best available data to determine event status for all Stroke events => CEC adjudicated event status when available, else site reported event status

If and only if the below criterion is met:

1. Patient has some in-hospital (#12153/ #9002) or follow-up (#12933/#14276) Event and Event occurred = Ischemic stroke, hemorrhagic stroke and undetermined stroke (concept IDs 2475, 2476 and 2477) associated with an in-hospital or follow-up Event Date (#14275/#14277) within 0-30 days of Procedure Start Date (#7000).

C. **In-hospital or 30 Day VARC Major or Life-Threatening Disabling Bleed**

Using best available data to determine event status for Hemorrhagic Stroke events=> CEC adjudicated event status when available, else site reported event status

If and only if any of the below criteria are met:

1. Patient has some follow-up Event and Event Occurred (#12933/#14276) = Major Bleeding or Life-Threatening Bleed associated with a follow-up Event Date (#14277) within 0-30 days of Procedure Start Date (#7000).
2. Patient has some in-hospital Event and Event Occurred (#12153/ #9002) = Unplanned Vascular Surgery or Intervention associated with their hospitalization and the decrease from Pre-Procedure Hemoglobin (#6030) to the lowest Post Procedure Hemoglobin (#13763) for the hospitalization is at least 3 g/dL.
3. Patient has some in-hospital Event and Event Occurred (#12153/#9002) = Bleeding at Access; Hematoma at Access; RP Bleed; GI Bleed; GU Bleed; Other Bleed; Hemorrhagic Stroke associated with their hospitalization and at least one of the following must be true:
    a. The decrease from Pre-Procedure Hemoglobin (#6030) to the lowest Post Procedure Hemoglobin (#13763) for the hospitalization is at least 3 g/dL.
    b. There are at least 2 units of RBC/Whole Blood Transfused (#13670).

(Note - transapical related event/E014 and transaortic related event/E015 had low rates and are retired. These would now map to "other" bleed/E22)

4. Patient died in-hospital (#10105 = Deceased) with Primary Cause of Death (10125) =vascular, CV hem or hem

5. Patient died in-follow-up (#10004 = Deceased) with Date of Death (#11006) within 0-30 days of Procedure Start Date (#7000) or Date of Death (#11006) missing and Date of Assessment (#11000) within 0-75 days of Procedure Start Date (#7000) and having Primary Cause of Death ((10125) = vascular, CV hem, or hem.

D. **Renal Failure - In-hospital AKI Stage III or In-hospital/30-Day New Requirement for Dialysis** - If and only if any of the below criteria are met and patient is not currently on dialysis (#13880) = No):
   1. Patient has a minimum 300% increase from Pre-Procedure Creatinine (#6050) to Post Procedure Creatinine (#13674).
   2. Patient has a minimum 0.5 mg/dL absolute increase from Pre-Procedure Creatinine (#6050)) to Post Procedure Creatinine (#13674) and a minimum 4 mg/dL Post Procedure Creatinine (#13674).
   3. Patient has some in-hospital Event and Event Occurred (#12153/#9002) or follow-up Event and Event Occurred (#12933/#14276) = New Requirement for Dialysis - associated with an in-hospital or follow-up Event Date (#14275/#14277) within 0-30 days of Procedure Start Date (#7000).

E. **In-hospital or 30-Day Moderate/Severe PVL** - If and only if either of the below criteria are met:
   1. Patient has Moderate or Severe follow-up Aortic Paravalvular Severity (#14504 = Moderate or Severe) associated with the latest follow-up Echocardiogram Date (#13593) * {in which there is documented Aortic Paravalvular Severity} within 23-75 days of Procedure Start Date (#7000).
   2. Patient has Moderate or Severe Post Procedure Aortic Paravalvular Severity (#14503 = Moderate or Severe) and no instance of the following:
      (Follow-up Aortic Regurgitation (#13527) = None) or (Follow-up Aortic Paravalvular Severity (#14504) = None, Mild, Moderate, or Severe) associated with some follow-up Echocardiogram Date (#13593) * within 23-75 days of Procedure Start Date (#7000).

      *Use Assessment Date (#11000) when Echo Date is missing

Note: Patients not meeting criteria for a given endpoint are assigned "No" status for that endpoint.

TABLE 2:

Variable	Type	Elements	Notes
Age function 1	Continuous*	DOB (2050); Arrival Date (3001)	Age of patient
Age function 2	Continuous*	DOB (2050); Arrival Date (3001)	# years >75
BSA (among males), per m^2	Continuous*	Sex (2060); Ht (6000); Wt (6005)	0.007184 x $HeightCm^{0.725}$ x $WeightKg^{0.425}$ (DuBois and DuBois formula)
BSA (among females)	Continuous*	Sex (2060); Ht (6000); Wt (6005)	
Ejection fraction	Continuous*	LVEF (13305)	
Hemoglobin function	Continuous*	Hemoglobin (6030)	
Platelet count - function 1	Continuous*	Platelets (13213)	
Platelet count - function 2	Continuous*	Platelets (13213)	Platelet count > 200k
Procedure date	Continuous*	Procedure start date (7000)	# Days since November 2011 (first approval of TAVR).

GFR function	Continuous*	DOB (2050); Arrival Date (3001) Black Race (2071) Sex (2060) Cr (6050)	GFR=186 * Creatinine $^{(-1.154)}$ x age $^{(-.203)}$ x 0.742 (if female) x 1.21 (if black) (MDRD equation)
Dialysis	Discrete	Dialysis (13880)	
Sex	Discrete	Sex (2060)	
Non-white or Hispanic	Discrete	Race (2070-2076)	
Left Main ≥ 50%	Discrete	Left Main Stenosis>=50% (13260)	
Proximal LAD ≥ 70%	Discrete	Proximal LAD >=70% (13301)	
Prior MI	Discrete	Condition History (12903) =MI and Condition Occurrence (14264) =yes	
Endocarditis	Discrete	Condition History (12903) =Endocarditis and Condition Occurrence (14264) =yes	
Prior stroke or TIA	Discrete	Condition history (12903) is TIA or CVA AND Occurrence (14264) = yes	
Carotid stenosis	Discrete	Condition history (12903) is Carotid Stenosis AND Occurrence (14264) = yes	
Prior PAD	Discrete	Condition history (12903) =PAD AND Occurrence (14264) = yes;	
Current/recent smoker	Discrete	[Current/Recent Smoker (v2 #12176 up to 12/31/2020) is yes] or [Tobacco Use (4625) is current-every day, current-some days, smoker – current status unknown	

Diabetes	Discrete	Condition history (12903) =Diabetes AND Occurrence (14264) = yes	
Afib/flutter	Discrete	Condition history (12903) is (AFib/Aflutter (in v2, retiring 12/31/2020), (AFib), or (Aflutter] AND [Occurrence (14264) = yes];	
Conduction defect	Discrete	Condition history (12903) =Conduction Defect AND Occurrence (14264) = yes	
Chronic lung disease, severe	Discrete	Chronic Lung Disease Severity (13904) =severe	
Home oxygen	Discrete	Home Oxygen (13881)	
Hostile chest	Discrete	Condition history (12903) =Hostile Chest AND Occurrence (14264) = yes	
Porcelain aorta	Discrete	Condition history (12903) = Porcelain Aorta AND Occurrence (14264) = yes	
Not femoral access site	Discrete	Valve Sheath Access Site (13507)	
Pacemaker	Discrete	Procedure history (12905) =Pacemaker AND Occurrence (14268) = yes	
Previous ICD	Discrete	Procedure history (12905) =Previous ICD AND Occurrence (14268) = yes	
Prior PCI	Discrete	Procedure history (12905) =Prior PCI AND Occurrence (14268) = yes	
Prior CABG	Discrete	Procedure history (12905) =Prior CABG AND Occurrence (14268) = yes	
Prior cardiac operations, 1	Discrete	# Previous Cardiac Surgeries (13697)	
Prior cardiac operations, 2 or more	Discrete	# Previous Cardiac Surgeries (13697)	

Prior aortic valve procedure	Discrete	Procedure history (12905) =AV Procedure AND Occurrence (14268) = yes	
Prior non-aortic valve procedure	Discrete	Procedure history (12905) =MV Procedure, or TV Procedure or PV Procedure AND Occurrence (14268) = yes	
Aortic etiology, degenerative	Discrete	AV Disease Etiology (13442)	
Aortic valve morphology-tricuspid (# of leaflets)	Discrete	Valve Morphology (13468)	
Aortic regurgitation, ≥ moderate	Discrete	Aortic Regurgitation (13477)	
Mitral regurgitation, ≥ moderate	Discrete	Mitral Regurgitation (13672)	
Tricuspid regurgitation, ≥ moderate	Discrete	Tricuspid Regurgitation (13318)	

Acuity category 2	Discrete	Procedure status (7025) Prior Cardiac Arrest w/in 24 hrs. (14267) Prior Cardiogenic Shock w/in 24 hrs. (13175) Pre-procedure inotropes (13643) Pre-procedure Mechanical Assist Device (7422, 7424)	Acuity category 2 includes both of the following: 1) Procedure status= urgent AND 2) No shock, inotropes, mechanical assist device or cardiac arrest
Acuity category 3	Discrete		Acuity category 3 includes all 3 of the following: 1) Procedure status is elective or urgent 2) Pt presented with pre-procedure shock, inotropes, OR mechanical assist device 3) No prior cardiac arrest w/in 24 hrs. prior to procedure

Acuity category 4	Discrete		Acuity category 4 is defined as either or both of the following: 1) Procedure status is emergency or salvage, or 2) Patient had cardiac arrest w/in 24 hrs. prior to procedure.
Unable to walk	Discrete	5 Meter Walk (13919) =unable to walk	
Five-meter walk speed (per 0.2m/sec)	Continuous	5 Meter Walk (13919, 13201, 13919) speeds.	Missing 5-meter walk speed is imputed as the median of all non-missing walk tests among patients who are eligible in the model. In 2017q2 the median score was *0.6.*
KCCQ (baseline) overall score	Continuous	KCCQ (#13846,48,49,51,53,55,57, 59, 61, 63, 65, 67)	Missing KCCQ is imputed as the median of all non-missing scores among patients who are eligible in the model. In past years, the median score was 41.67 for 30-day RAM.

***** *Linear or continuous variables are typically variables that are numbers (weight, age, BMI). These variables have coefficients or weights that change based on the value of the variables*